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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|------------------------------|------------------|
| 09/899,702 | 07/05/2001 | Robert J. D' Amato | 05213-0910 (43170-219505) | 8386 |

7590 03/13/2002
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EXAMINER

QAZI, SABIHA NAIM

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1616

DATE MAILED: 03/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/899,702

Applicant(s)
Robert J. D'Amato et al.

Examiner
Sabiha Qazi

Art Unit
1616



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 10, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above, claim(s) 3, 4, and 6-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, and 5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 3, 4, and 6-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

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First Office Action on Merits

Claims 1-31 are pending.

No claim is allowed.

Claims 1, 2 and 5 are rejected, others are withdrawn from consideration as non elected invention.

Response with election of group I , and election of species of claim 2 with traverse, filed in paper no. 4 is hereby acknowledged. Amendments and new claims filed in paper no. 5, dated 1/15/02 are entered but are not examined. These claims are independent claims and are drawn to different substituents. Method of use will not be joined with the compounds as requested, for the reasons set forth in our previous office action. Compound claims are broad and belong to various subclasses, it would be a burden on the Examiner to search all the invention. Restriction is therefore, considered proper and is now made FINAL.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78). All pending applications and/or patents related to the instant subject matter must be disclosed for any double patenting.

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Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, and 5 rejected under 35 U.S.C. 102(e) as being anticipated by Sachdeva et al. (US Patent 6,054,598). See compound no 10 in scheme which is 2-ethoxy estradiol (see also example 6B in col. 13) and 2-methoxy estradiol compound no. 1, (see table 1 in cols. 15 and 16). Same compound is instantly claimed see when in instant claims when Ra O-R (R is ethyl); Rg is C(H)-OH; Ro and Rb is H; Z' is OH; Z'' is CH₂. In compound 1, Ra is OCH₃.

3. Claims 1, 2, and 5 rejected under 35 U.S.C. 102(e) as being anticipated by Nambara et al. (DN 82:43650, HCAPLUS, abstract of Chem. Pharm. Bull. (1974), 22(10), 2455-7). See compound of RN 54502-29-3 and 54502-31-7.

The compound contains Ra = O-R, (R is lower alkyl); Rb = H; Z' = C-OH; R0 = H; Z'' = CH₂; Rg = C-OH.

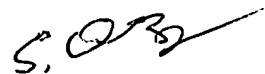
3. Claims 1, 2, and 5 rejected under 35 U.S.C. 102(e) as being anticipated by

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D'Amato et al. (US Patent 5,504,074). See 1st two compounds in Table 2, col.; Table 1 see line 32, 37, 38, 41, in col. 8.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha N. Qazi, whose telephone number is (703) 305-3910. The examiner can normally be reached on Monday through Friday from 8 a.m. to 6 p.m. The fax phone number for this Group is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



Sabiha N. Qazi, Ph.D.

Primary Examiner

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3/9/02